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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/082,925	02/26/2002	John Edward More	697.004US2	4853

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EXAMINER	
MOHAMED, ABDEL A	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 03/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/082,925	MORE ET AL.	
	Examiner	Art Unit	
	Abdel A. Mohamed	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 February 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *27-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *27-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/142,348.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 3.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

ACKNOWLEDGMENT OF PRIORITY, PRELIMINARY AMENDMENT, IDS, STATUS OF THE APPLICATION AND CLAIMS

1. This application is a Continuation of Serial No. 09/142,348 filed 1/25/99, now U.S. Patent No. 6,387,877, which is filed under 35 U.S.C. 371 having a filing date of 3/7/97 of PCT/GB/00642. Acknowledgement is made of Applicant's claim priority based on United Kingdom Application Number 9604921.8 having a filing date of 3/8/96. Receipt is acknowledged of papers submitted under 35 U.S.C. § 119, which papers have been placed of record in the file of parent application Serial No. 09/142,348. The preliminary amendment and the information disclosure statement (IDS) and Form PTO-1449 filed 2/26/02 are acknowledged, entered and considered. In view of Applicant's request claims 1-26 have been canceled and claims 27-34 have been added. Thus, claims 27-34 are pending in the application. With respect to the IDS, the references cited therewith on Form PTO-1449 are not provided in the instant application. However, as *per* Applicant's request, since the cited references were considered previously in parent application Serial No. 09/142,348; pursuant to 37 CFR § 1.98(d), the references cited in Form PTO-1449 in this application have been considered and signed as requested by Applicant.

2. The specification is objected because there are no Headings disclosed in the disclosure and the following guidelines illustrate the preferred layout and content for patent application. These guidelines are suggested for the Applicant's use.

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) TITLE OF THE INVENTION.

(b) CROSS-REFERENCE TO RELATED APPLICATIONS.

(c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.

(d) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC (See 37 CFR 1.52(e)(5) and MPEP 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text are permitted to be submitted on compact discs.) Or

REFERENCE TO A "MICROFICHE APPENDIX" (See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.)

(e) BACKGROUND OF THE INVENTION.

(1) Field of the Invention.

(2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.

(f) BRIEF SUMMARY OF THE INVENTION.

(g) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).

(h) DETAILED DESCRIPTION OF THE INVENTION.

(i) CLAIM OR CLAIMS (commencing on a separate sheet).

(j) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).

(k) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

OBJECTIONS TO TRADEMARKS AND THEIR USE

3. The use of the trademarks "Aerosil™" and "Zenalb™" has been noted in this application. The trademarks have not been capitalized, they should be capitalized wherever they appear and be accompanied by the generic terminology. Although, the use of trademarks are permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in a manner which might adversely affect its validity as trademarks.

Further, the specification, which specifies the generic terminology should include, published product information sufficient to show that the generic terminology or the generic description are inherent in the article referred by the trademarks. These description requirements are made because the nature and composition of articles denoted by trademarks can change and affect the adequacy of the disclosure.

STATEMENT OF STATUTORY BASIS, 35 U.S.C. 101

4. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 31-33 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153USPQ 678 (Bd. App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966). A "use" is not a proper of use claims.

CLAIMS REJECTION-35 U.S.C. § 112 2nd PARAGRAPH

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 27-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 27-34 are indefinite in the recitation the acronyms "AAG" (claims 27-34) and "LPS" (claims 27-29), respectively. Use of the full terminology at least in the first occurrence would obviate this rejection.

Claim 27 is indefinite in the recitation "substantially free of LPS" because it is unclear as to how much the alpha-1-acid glycoprotein (AAG) is free of lipopolysaccharide (LPS). If Applicant intends to claim that the AAG has a LPS concentration of less than or equal to 0.1 Eu/mg AAG, then the phrase "substantially free of LPS" appears to contradictory because the exact amount is disclosed, and as such, the phrase "substantially free" is superfluous. Deletion of this phrase is suggested or appropriate clarification is required.

Claims 31-33 provide for the use of AAG in therapy (claim 31), in treatment of drug toxicity (claim 32) and in the manufacture of medicament (claim 33), respectively; but, since the claims do not set forth any steps involved in the method/process, it is unclear what method/process Applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

CLAIMS REJECTION-35 U.S.C. § 102(b)

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 27-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Libert et al. (J. Exp. Med., Vol. 180, pp. 1571-1575, October 1994).

The reference of Libert et al. discloses α-1-acid glycoprotein (AAG) wherein the AAG has purity of over 99% and no contaminant were observed. The amount of endotoxin (LPS) was less than 0.11 ng endotoxin/mg protein. Thus, clearly showing that AAG disclosed in the reference is substantially free of LPS (See e.g. Materials and Methods, particularly page 1571, right column) as directed to claims 27-29. The reference clearly teaches the *in vivo* administration of AAG formulation to mice by intraperitoneal injection and intravenous injection (See e.g. page 1571, particularly summary and last paragraph of left column). Thus, for a formulation to be administered *in* vivo, the formulation has to be in a pharmaceutical composition free of pyrogenic material and microbial agents including virus (i.e., the material has to be a virus depleted preparation) and as such meet the limitations of claims 30 and 34.

With respect to claims 31-33, the reference discloses a pyrogen free product/composition of an AAG, which is over 99% pure i.e., substantially free of LPS and administered *in vivo* (See e.g., page 1571, Materials and Methods). However, the reference does not disclose the intended use of the AAG for "therapy", "treating of drug toxicity" and (manufacturing medicament) as claimed in claims 31, 32 and 33, respectively. Nevertheless, a statement of usefulness or contemplated use of a claimed compound or composition in a claim is usually given little weight in distinguishing over the prior art. *In re Maeder et al.* (CCPA 1964) 337 F2d 875, 143 USPQ 248; *In re Riden et al.* (CCPA 1963) 318 F2d 761, 138 USPQ 112; *In re Sinex* (CCPA 1962) 309 F2d 488, 135 USPQ 302. Further, it is well established that the intended use of a compound (e.g., a polypeptide or a protein or a glycoprotein) does not impart patentability to the

compound. *In re Spada,* 911 F.2d 705, 15 USPQ2d 1655 (Fed. Cir. 1990) (The discovery of a new property or use of a previously known composition, even when that property and use are unobvious from the prior art, can not impart patentability to claims to the known composition); *In re Pearson*, 494 F.2d 1399, 1403, 181 USPQ 641, 644 (CCPA 1974) (intended use of an old composition does not render composition claims patentable); *In re Zierden*, 411 F.2d 1325, 1328, 162 USPQ 102, 104 (CCPA 1969).

In regard to the various concentrations of LPS in AAG preparation as claimed in claims 27--29; however, the claims do not define the various concentrations as structural limitations, rather, the claims define the various concentrations of LPS as properties of AAG preparations. Thus, the various concentrations of the contaminants LPS in AAG solutions are inherent properties, which are characteristics when AAG containing preparations are purified. Thus, in the absence of evidence to the contrary or specific structural limitations, the claimed composition/product disclosed by the reference anticipates claims 27-34 as drafted.

7. Claims 27-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Boutten et al. (European Journal of Immunology, Vol. 22, No. 10, pp. 2687-295, Oct. 1992).

The reference of Boutten et al. discloses a pyrogen free product/composition of an AAG wherein the AAG preparation in PBS were passed through a Detoxigel column, and then filter sterilized through a 0.2 μm filter to remove the contaminant LPS. Thus, clearly showing that AAG disclosed in the reference is substantially free of LPS and is a

virus depleted preparation. To the extent that AAG is in a physiological buffer it is considered to be a pharmaceutical composition (See e.g. abstract, page 2688 and particularly under 2.2 preparation of AGP) as directed to claims 27-30 and 34.

With respect to claims 31-33, the reference discloses a pyrogen free product/composition of an AAG, which is substantially free of LPS and other contaminants, which may include viruses. However, the reference does not disclose the intended use of the AAG for "therapy", "treating of drug toxicity" and (manufacturing medicament) as claimed in claims 31, 32 and 33, respectively. Nevertheless, a statement of usefulness or contemplated use of a claimed compound or composition in a claim is usually given little weight in distinguishing over the prior art. *In re Maeder et al.* (CCPA 1964) 337 F2d 875, 143 USPQ 248; *In re Riden et al.* (CCPA 1963) 318 F2d 761, 138 USPQ 112; *In re Sinex* (CCPA 1962) 309 F2d 488, 135 USPQ 302. Further, it is well established that the intended use of a compound (e.g., a polypeptide or a protein or a glycoprotein) does not impart patentability to the compound. *In re Spada,* 911 F.2d 705, 15 USPQ2d 1655 (Fed. Cir. 1990) (The discovery of a new property or use of a previously known composition, even when that property and use are unobvious from the prior art, can not impart patentability to claims to the known composition); *In re Pearson*, 494 F.2d 1399, 1403, 181 USPQ 641, 644 (CCPA 1974) (intended use of an old composition does not render composition claims patentable); *In re Zierden*, 411 F.2d 1325, 1328, 162 USPQ 102, 104 (CCPA 1969).

In regard to the various concentrations of LPS in AAG preparation as claimed in claims 27--29; however, the claims do not define the various concentrations as

structural limitations, rather, the claims define the various concentrations of LPS as properties of AAG preparations. Thus, the various concentrations of the contaminants LPS in AAG solutions are inherent properties, which are characteristics when AAG containing preparations are purified. Thus, in the absence of evidence to the contrary or specific structural limitations, the claimed composition/product disclosed by the reference anticipates claims 27-34 as drafted.

8. Claims 27-34 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 95/07703 (ALPHA THERAPEUTICS CORP).

The reference of WO 95/07703 discloses a pyrogen free product/composition of an AAG wherein the AAG preparation has purity of over 99% and no contaminant were observed (See e.g., Summary of the Invention). Such purity is obtained by eluting AAG from the anion-exchange medium by using a high salt solution and then recovering, concentrating and washing by diafiltration/ultrafiltration or other suitable methods. Thus, clearly showing that AAG disclosed in the reference is substantially free of LPS and is a virus depleted preparation. To the extent that AAG is in a physiological buffer it is considered to be a pharmaceutical composition (See e.g., page 4, lines 17-26 and Examples 1-5) as directed to claims 27-30 and 34.

With respect to claims 31-33, the reference discloses a pyrogen free product/composition of an AAG, which is over 99% pure i.e., substantially free of LPS and other contaminants, which may include viruses. However, the reference does not disclose the intended use of the AAG for "therapy", "treating of drug toxicity" and

(manufacturing medicament) as claimed in claims 31, 32 and 33, respectively. Nevertheless, a statement of usefulness or contemplated use of a claimed compound or composition in a claim is usually given little weight in distinguishing over the prior art. *In re Maeder et al.* (CCPA 1964) 337 F2d 875, 143 USPQ 248; *In re Riden et al.* (CCPA 1963) 318 F2d 761, 138 USPQ 112; *In re Sinex* (CCPA 1962) 309 F2d 488, 135 USPQ 302. Further, it is well established that the intended use of a compound (e.g., a polypeptide or a protein or a glycoprotein) does not impart patentability to the compound. *In re Spada,* 911 F.2d 705, 15 USPQ2d 1655 (Fed. Cir. 1990) (The discovery of a new property or use of a previously known composition, even when that property and use are unobvious from the prior art, can not impart patentability to claims to the known composition); *In re Pearson*, 494 F.2d 1399, 1403, 181 USPQ 641, 644 (CCPA 1974) (intended use of an old composition does not render composition claims patentable); *In re Zierden*, 411 F.2d 1325, 1328, 162 USPQ 102, 104 (CCPA 1969).

In regard to the various concentrations of LPS in AAG preparation as claimed in claims 27--29; however, the claims do not define the various concentrations as structural limitations, rather, the claims define the various concentrations of LPS as properties of AAG preparations. Thus, the various concentrations of the contaminants LPS in AAG solutions are inherent properties, which are characteristics when AAG containing preparations are purified. Thus, in the absence of evidence to the contrary or specific structural limitations, the claimed composition/product disclosed by the reference anticipates claims 27-34 as drafted.

CONCLUSION AND FUTURE CORRESPONDANCE

9. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abdel A. Mohamed whose telephone number is (571) 272-0955. The examiner can normally be reached on Monday through Friday from 7:30 a.m. to 5:00 p.m. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher S.F. Low, can be reached on (571) 272-0951. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306 for regular communications and (703) 305-7401 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

AAM Mohamed/AAM

March 1, 2004

Christopher S. F. Low

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